

MAY 23 2001

TECH CENTER 1600/2900

REMARKS

Claims 1-5, 12-15, 19, 27-28, 30 and 32 were rejected. Claims 1 and 13-14 are amended above. Applicants respectively request favorable reconsideration of the rejections and allowance of the present application in view of the above amendments and the following remarks.

The objection to claim 13 has been overcome by the above amendment.

The rejection of claims 1-5, 12-15, 19, 27-28, 30 and 32 under 35 USC 102(b) as anticipated by EP 0382531, Gurnett, was maintained. The Examiner stated in part that the Gurnett reference discloses that "when lipase is added prior to phase separation, the proteins are found in the aqueous (hydrophilic) phase" and that these proteins "exhibit the desired molecular weight characteristics of applicants claims." This rejection is traversed.

Applicants have amended claim 1 to further define the claimed composition as "substantially free of proteins which are membrane-bound in *Eimeria*." Support for the amendment is found on page 4, lines 1-5, of the application. No new matter has been added.

The amended claim 1 is not taught or suggested by the cited Gurnett reference. According to Gurnett, the "hydrophobic glycolipid linked proteins" partition into the hydrophilic phase of a Triton X-114 extraction only when lipase is added prior to phase separation. Gurnett describes these otherwise hydrophobic proteins (which partition into the detergent phase in the absence of lipase) as "membrane associated proteins" due to the presence of a "glycolipid membrane attachment anchor." The Gurnett

reference thus fails to teach or suggest the protein-containing composition of amended claim 1, in which the recited one or more proteins, or fragments thereof, are present in the hydrophilic phase of a Triton X-114 extract of *Eimeria* sporozoites and wherein the composition is substantially free of proteins which are membrane-bound in *Eimeria*, as are the hydrophobic proteins disclosed by Gurnett and relied on by the Examiner. Accordingly, Applicants ask that the Section 102(b) rejection be withdrawn.

Claims 14 and 28 were rejected under 35 USC 112, first paragraph, for an alleged lack of written description. This rejection also is traversed.

Claim 14 has been amended to recite Quil A as the adjuvant. Support for the amendment is found at page 19, line 19, and page 26, line 18, of the specification.

Quil A is clearly understood in the art as a common adjuvant for veterinary use. Attached as support are two references relating to vaccine adjuvants, in which Quil A is identified. Specifically, Applicants have highlighted the relevant portions of the references, which include the following: On the first page of the "Adjuvant Guide" (from Cedarlane Laboratories Limited), the guide identifies Quil A as an example of a "true" adjuvant, stating that "[s]ome examples of 'true adjuvants' are: aluminum hydroxide; aluminum phosphate; calcium phosphate; non-ionic block copolymers surfactants...; and Quil A." (emphasis added)

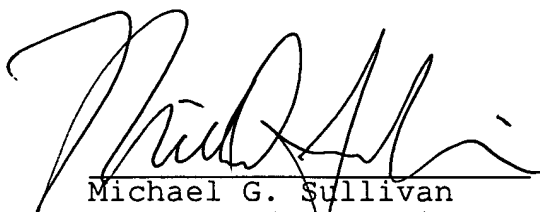
As additional support, Applicants also enclose copies of claims from recently issued U.S. Patents, which claims recite Quil A as an adjuvant. Indeed, one of these patents issued only last month on April 27, 2001. Accordingly, Applicants ask for

the above reasons that the Section 112, first paragraph, rejection also be withdrawn.

In view of the above remarks, it is believed that the application is in condition for allowance. Favorable action thus is solicited.

In the event this paper is not considered to be timely filed, Applicants hereby petition for the appropriate extension of time. Any fee for such an extension, along with any other fees due in this application, may be charged to our Deposit Account No. 02-2334.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michael G. Sullivan", is written over a horizontal line.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended four times) A composition free of whole *Eimeria* parasites, which comprises one or more proteins, or fragments thereof, wherein said proteins:

(a) are present in the hydrophilic phase of a Triton X-114 (tertoctylphenoxypoly (ethoxyethanol)) extract of *Eimeria* sporozoites[ wherein Triton X-114 is a tertoctylphenoxypoly (ethoxyethanol)]; and

(b) have molecular masses of 26 - 30 kDa  $\pm$  5 kDa when determined by SDS-PAGE under reducing conditions[.];

and wherein said composition is substantially free of proteins which are membrane-bound in *Eimeria*.

13. (twice amended) A vaccine composition according to claim [11 or] 12, wherein said vaccine comprises an adjuvant.

14. (Amended three times) A composition according to claim 13, wherein the adjuvant is [a saponin] Quil A.